

114TH CONGRESS  
2D SESSION

# H. R. 5479

To provide for programs under the Department of Health and Human Services to improve newborn screening, evaluation, and intervention for critical congenital heart defect.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 2016

Ms. MCCOLLUM introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To provide for programs under the Department of Health and Human Services to improve newborn screening, evaluation, and intervention for critical congenital heart defect.

1       *Be it enacted by the Senate and House of Representa-*

2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Screening Hearts in

5       Newborns for Early Detection of Congenital Heart Defect

6       Act” or the “SHINE Act”.

1   **SEC. 2. PROGRAMS TO IMPROVE NEWBORN SCREENING,**  
2                   **EVALUATION, AND INTERVENTION FOR CRIT-**  
3                   **ICAL CONGENITAL HEART DEFECT.**

4       (a) STATEWIDE NEWBORN SCREENING PROGRAMS,  
5   EVALUATION AND INTERVENTION PROGRAMS AND INFOR-  
6   MATION SYSTEMS.—

7               (1) IN GENERAL.—The Secretary of Health and  
8   Human Services shall make awards of grants or co-  
9   operative agreements to States to—

10              (A) develop and improve, with respect to  
11   critical congenital heart defect, statewide new-  
12   born CCHD screening, evaluation, diagnosis,  
13   results reporting, data collection and surveil-  
14   lance, and intervention programs and systems;  
15   and

16              (B) assist in the recruitment, retention,  
17   education, and training of qualified personnel;  
18   for the purposes described in paragraph (2).

19              (2) PURPOSES.—For purposes of paragraph  
20   (1), the purposes described in this paragraph are the  
21   following:

22              (A) To develop and monitor the efficacy of  
23   statewide programs and systems for CCHD  
24   screening of newborns, evaluate and diagnose  
25   newborns referred from screening programs,  
26   and provide for educational and medical inter-

1           ventions for newborns identified with critical  
2           congenital heart defect (and other health condi-  
3           tions associated with hypoxemia).

4           (B) To provide for early intervention, in-  
5           cluding—

6               (i) referral to and delivery of informa-  
7               tion and services, relating to CCHD  
8               screening, evaluation, and diagnosis, by en-  
9               tities and agencies, including clinical, com-  
10              munity, consumer, and parent-based agen-  
11              cies and organizations; and

12              (ii) other programs mandated by part  
13              C of the Individuals with Disabilities Edu-  
14              cation Act (20 U.S.C. 1431 et seq.), which  
15              offer programs specifically designed to  
16              meet the unique needs of newborns with  
17              critical congenital heart defect and which  
18              establish and foster family-to-family sup-  
19              port mechanisms critical in the first  
20              months after a newborn is identified with  
21              critical congenital heart defect.

22           (C) To collect data on statewide newborn  
23           CCHD screening and screening of secondary  
24           conditions and evaluation and intervention pro-  
25           grams and systems that can be applied for

1           quality improvement, research, program evalua-  
2           tion, and policy development.

3           (D) To encourage the adoption by State  
4           agencies of models described in subparagraph  
5           (E).

6           (E) To provide for other activities, which  
7           may include the development of efficient models  
8           to ensure that newborns who are identified with  
9           critical congenital heart defect through screen-  
10          ing receive follow-up by a qualified health care  
11          provider.

12         (b) CCHD INFORMATION AND SURVEILLANCE SYS-  
13         TEMS AND APPLIED RESEARCH.—

14           (1) CENTERS FOR DISEASE CONTROL AND PRE-  
15           VENTION.—In accordance with the recommendations  
16           described in paragraph (5), the Secretary, acting  
17           through the Director of the Centers for Disease  
18           Control and Prevention, shall make awards of grants  
19           or cooperative agreements to provide technical as-  
20           sistance to State agencies to complement intramural  
21           programs and to conduct applied research related to  
22           newborn CCHD screening, evaluation and interven-  
23           tion programs, and data collection and information  
24           systems, such as—

(A) standardized procedures for data management and program effectiveness to ensure quality monitoring of newborn CCHD screening, evaluation, diagnosis, and intervention programs and systems;

(B) evaluation of the current capacity of existing population-based State surveillance and tracking to monitor the effectiveness of newborn CCHD screening to reduce infant mortality and morbidity;

(C) provision of technical assistance on data collection and management, including leveraging an electronic health record framework for critical congenital heart defect data and reporting;

(D) study of the costs and effectiveness of newborn CCHD screening and secondary targets and nontarget conditions associated with hypoxemia;

(E) evaluation and intervention programs and systems conducted by State-based programs in order to answer issues of importance to State and national policymakers;

(F) further study of the causes and risk factors for critical congenital heart defect;

(G) study of the effectiveness of newborn CCHDs screening, followup diagnostics, medical evaluations and intervention programs and systems by assessing the health, intellectual, and social developmental, cognitive, and neurodevelopmental status of such children as they grow and enter school age; and

(H) data reporting by State agencies to the Department of Health and Human Services regarding CCHD screening conducted as part of State-based birth defects monitoring and long-term follow up programs for the purpose of providing appropriate services.

(2) NATIONAL INSTITUTES OF HEALTH.—In accordance with the recommendations described in paragraph (5), the Director of the National Institutes of Health shall, for purposes of this section—

(A) conduct a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, follow-up diagnostic tools, and studies on efficacy of intervention and related research; and

(B) acting through the National Library of Medicine of the National Institutes of Health,

1 assist the Secretary with the development and  
2 deployment of expanded coding terminology for  
3 pulse oximetry screening for CCHD and follow-  
4 up diagnostic testing related to screening and  
5 integrating results into electronic medical  
6 records and as part of interoperability with  
7 public health information systems.

8 (3) HEALTH RESOURCES SERVICES ADMINIS-  
9 TRATION.—In accordance with the recommendations  
10 described in paragraph (5), the Administrator of the  
11 Health Resources and Services Administration shall,  
12 in coordination with the Director of the Centers for  
13 Disease Control and Prevention—

14 (A) guide the assessment and improvement  
15 of screening standards and infrastructure need-  
16 ed for the implementation of a public health ap-  
17 proach to point of care screening for congenital  
18 heart defects; and

19 (B) coordinate and collaborate in assisting  
20 States to establish newborn CCHD screening  
21 and other secondary conditions associated with  
22 hypoxemia, evaluation, diagnosis, and interven-  
23 tion programs and systems under paragraph (1)  
24 and to develop a data collection system under  
25 paragraph (2).

1                             (4) FDA CENTER FOR DEVICES AND RADIO-  
2 LOGICAL HEALTH.—In accordance with the rec-  
3 ommendations described in paragraph (5), the Cen-  
4 ter for Devices and Radiological Health of the Food  
5 and Drug Administration shall provide guidance to  
6 health care providers, industry, and staff of the  
7 Food and Drug Administration on pulse oximeters  
8 and the unique role of pulse oximetry in screening  
9 neonatal patients.

10                            (5) RECOMMENDATIONS.—The recommenda-  
11 tions described in this paragraph are the following  
12 recommendations contained in the plan of action of  
13 the Interagency Coordinating Committee on New-  
14 born and Child Screening established under section  
15 114 of the Public Health Service Act (42 U.S.C.  
16 300b–13):

17                            (A) The recommendation for the Centers  
18 for Disease Control and Prevention to fund sur-  
19 veillance activities to monitor the CCHD link to  
20 infant mortality and other health outcomes.

21                            (B) The recommendation for the National  
22 Institutes of Health to fund research activities  
23 to determine the relationships among the  
24 screening technology, diagnostic processes, care  
25 provided, and health outcomes of affected

1           newborns with CCHD as a result of prospective  
2           newborn screening.

3           (C) The recommendation for the Health  
4           Resources and Services Administration to guide  
5           the development of screening standards and in-  
6           frastructure needed for the implementation of a  
7           public health approach to point of service  
8           screening for critical congenital cyanotic heart  
9           defect.

10          (D) The recommendation for the Health  
11          Resources and Services Administration to fund  
12          the development of, in collaboration with public  
13          health and health care professional organiza-  
14          tions and families, appropriate education and  
15          training materials for families and public health  
16          and health care professionals relevant to the  
17          screening and treatment of CCHD.

18          (6) CONSULTATION.—In carrying out programs  
19          under this subsection, the Administrator of the  
20          Health Resources and Services Administration, the  
21          Director of the Centers for Disease Control and Pre-  
22          vention, and the Director of the National Institutes  
23          of Health shall collaborate and consult with other  
24          Federal agencies; State and local agencies, including  
25          those responsible for newborn screening and early

1 intervention services under the Medicaid program  
2 under title XIX of the Social Security Act (42  
3 U.S.C. 1396 et seq.), under the Children's Health  
4 Insurance Program under title XXI of the Social Se-  
5 curity Act (42 U.S.C. 1397aa et seq.) (State Chil-  
6 dren's Health Insurance Program), under the Ma-  
7 ternal and Child Health Block Grant Program under  
8 title V of the Social Security Act (42 U.S.C. 701 et  
9 seq.), and under part C of the Individuals with Dis-  
10 abilities Education Act (20 U.S.C. 1431 et seq.);  
11 consumer groups of, and those that serve, individ-  
12 uals with congenital heart defect and families of  
13 such individuals; appropriate national medical and  
14 other health and education specialty organizations;  
15 persons living with critical congenital heart defect  
16 and families of such persons; other qualified profes-  
17 sional personnel who are proficient in congenital  
18 heart defect, CCHD, and related conditions, and  
19 who possess the specialized knowledge, skills, and at-  
20 tributes needed to serve newborns, infants, toddlers,  
21 and children diagnosed with congenital heart defect  
22 and families of such newborns, infants, toddlers, and  
23 children; third-party payers and managed care orga-  
24 nizations; and related commercial industries.

(7) POLICY DEVELOPMENT.—The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate to develop and update recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical, and other health and education professional-based organizations, with respect to newborn screening, evaluation, diagnosis, and intervention programs and systems. Such recommendations and updates shall be made available on the public Web site of the Department of Health and Human Services.

16 (c) DEFINITIONS.—For purposes of this section:

(1) The term “CCHD” means critical con-  
genital heart defect.

24 (d) AUTHORIZATION OF APPROPRIATIONS.—There is  
25 authorized to be appropriated such sums as may be nec-

1 essary to carry out this section for each of fiscal years  
2 2017 through 2021.

